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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,577	07/21/2003	Xin Yuan Hu	43056/287638	7506

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/624,577	Applicant(s) HU ET AL.	
	Examiner Michele Flood	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 7, 2005. Further acknowledgment is made of Applicant's cancellation of Claims 1-3 and newly submitted Claims 4-6.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-6 are under examination.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Newly applied as necessitated by amendment.

The specification on pages 3, line 10, page 6, line 8 and page 7, line 2, as set forth in the amendment filed on February 7, 2005, now discloses a Chinese medicine formulation comprising the following ingredients: "Gardenia (*Furctus Gardeniae*)", "Weeping Forsythiae (*Fructus Forsythiae*)", "Basket fern (*Rhizoma Crytomii*)", "Mint (*Herba Menthae*)" and "Liquorice (*Radix Glycyrrhizae*)". However, the specification as originally filed did not disclose a composition wherein the source of the particular aforementioned claim-designated ingredients were obtained from the aforementioned claim-designated plant parts. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "Gardenia (*Furctus Gardeniae*)" or "Weeping Forsythiae (*Fructus Forsythiae*)" or "Basket fern (*Rhizoma Cyrtomii*)" or "Mint (*Herba Menthae*)" or "Liquorice (*Radix Glycyrrhizae*)" in Claims 4-6. Newly applied as necessitated by amendment.

The claims, as set forth in the amendment filed on February 7, 2005, now recite a medicinal formulation comprising a decoction with water of claim-designated ingredients, including the aforementioned ingredients. However, the specification as originally filed provides only for a composition comprising a decoction comprising gardenia, weeping forsythiae, basket fern, mint and liquorice. In other words, the specification as originally filed does not provide for a composition wherein the plant material of the gardenia is fruit of gardenia; wherein the plant material of the weeping forsythiae is fruit of weeping forsythiae, wherein the plant material of basket fern is *Rhizoma Cyrtomii*; wherein the plant material of the mint is mint herb; and, wherein the plant material of the liquorice is root of liquorice. Insertion of the above mentioned claim limitations have no support in the as-filed specification. The insertion of the limitations are a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera

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which would show possession of the concepts for a composition comprising the aforementioned ingredients wherein the source of the aforementioned ingredients are obtained from the aforementioned claim-designated plant parts. There is only one exemplified composition comprising Scutellaria root, gardenia, Honeysuckle flower, Weeping forsythia, dried Rehmannia root, Gypsum, Flos chrysanthemi indici, Basket fern, Balloon flower root, mint, Arctium fruit and Liquorice. Nowhere in the specification as originally filed does Applicant either disclose or suggest that the aforementioned plant ingredients are obtained from the plant source material as presently amended. This is not sufficient support for the new aforementioned genera. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitations are considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitations could not be found in the present specification, the recitation of the claim limitations is deemed new matter. In an attempt to indicate that the claim limitations of independent Claims 4-6 is not new matter, the Office notes that in the "REMARKS", filed on February 7, 2005, Applicant argues that the amendment of the claims introducing the Latin genus-species name for each of the claim-designated ingredients is appropriate "because the new claims and the amendments to the specification do not introduce new matter." However, Applicant's

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argument is not persuasive because the specification as originally filed did not direct the claimed invention to a composition wherein the source of the particular aforementioned claim-designated ingredients were obtained from the aforementioned claim-designated plant parts. Moreover, insertion of the claim limitations of "Gardenia (*Furctus Gardeniae*)", "Weeping Forsythiae (*Fructus Forsythiae*)", "Basket fern (*Rhizoma Crytomii*)", "Mint (*Herba Menthae*)" and "Licorice (*Radix Glycyrrhizae*)" are generally not considered as "Latin genus-species names" for each of the instantly claimed ingredients, but are generally considered as common names or traditional/ethnopharmacological name of the claim-designated plant materials. For example, while the term "Flos Chrysanthemi indicii" is known in the art of traditional Chinese herbal medicine as the common name or traditional/ethnopharmacological name for the flower of the chrysanthemum plant, the Latin genus-species name of the plant is *Chrysanthemum indicum* L. var. *procumbens* (Lour.) Nakai, as evidenced by the teachings of Hong-Yen Hsu, Ph.D. et al. in Oriental Materia Medica: A Consise Guide (1986), Oriental Healing Arts Institute of the United States, U.S.A. See pages 71, and 117-120. As the above-mentioned claim limitations could not be found in the originally filed specification, the recitation of the claim limitations are deemed new matter; and, therefore they must be omitted from the claim language, unless Applicant can particularly point to the originally filed specification for literal support.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

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The metes and bounds of Claims 4-6 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical and animal matter noted in this application.

Claims 4-6 are rendered vague and indefinite by the term "Basket fern (*Rhizoma Cyrtomii*)" because it is uncertain as to the subject matter Applicant intends to direct the instantly claimed invention because the term "Basket fern" is not recognized in the art as "*(Rhizoma Cyrtomii)*". See

http://www.fzrm.com/plantextracts/Basket_Fern_extract.htm;

http://www.tcm.basics.com/materiamedica/rhizoma_dryopteris_crassirhizomae.htm;

<http://rainforest-australia.com/Basket%20Fern.htm>;

<http://www.sdferrn.com/common.htm>; and,

<http://classes.hortla.wsu.edu/hort232/list1/Cyrtomium.html>, wherein none of the cited websites indicate that Basket fern is a synonym of the term "*Rhizoma Cyrtomii*".

Therefore, the Examiner's preliminary analysis and extensive search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature.

Claim Objections

Claims 4-6 are objected to because of the following informalities: There is an apparent misspelling in line 3. Applicant may overcome the objection by replacing ""*Furctus*" with *Fructus*. Please note that similar misspellings were found in the specification. Appropriate correction is required.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Examiner
Art Unit 1654

MCF
May 12, 2005